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AND FEDERAL EXPRESS

May 12, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: BASF Corporation's Comments on FDA's Interim Final Rule on the Registration of Food Facilities (Docket No. 2002N-0276)

Dear Sir:

In response to the Food and Drug Administration's (FDA) notice of the reopening of the comment period for the interim final rule entitled "Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," BASF Corporation is respectfully submitting comments. As stated in the interim final rule (IFR), FDA intended to reopen the comment period after affected persons had experience with the systems, timeframes and data elements associated with the registration requirements. The reopening of the comment period, as published in the Federal Register on April 14th, 2004 (*69 Fed. Reg. 197660*), is consistent with that intent and requests comments with regard to a limited set of registration issues.

Based in Mt. Olive, New Jersey, BASF Corporation (BC) is the North American affiliate of BASF Aktiengesellschaft (BASF AG), Ludwigshafen, Germany. BC's diverse product mix includes chemicals, coatings, plastic, colorants, and health and nutritional products. Many of these products, which are either manufactured here in the U.S. or imported from our foreign affiliates, have applications in food as food additives. In response to the IFR requiring registration for domestic and foreign facilities manufacturing, processing, packing or holding food for human or animal consumption in the United States, BC registered 10 domestic facilities. In addition, BC acts as the U.S. agent in charge and assumed registration responsibilities for 13 foreign affiliate facilities importing food for consumption into the United States.

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BASF supports Congress and the FDA in efforts to protect the U.S. food supply from threatened or actual terrorist attacks. Indeed, the registration process for both our domestic and foreign affiliate's facilities was completed in a timely fashion. Although BC has not done an in depth analysis of the direct costs associated with this process, we believe that FDA's estimates of the costs are low given the immense effort put forth by BC in the analysis of the rule, determining the implications for business, disseminating information to affected facilities, and the implementation of plans to ensure compliance. We acknowledge that at this time FDA is requesting specific information in an attempt to improve it's economic analysis, in part, with regard to the cost to foreign facilities of hiring and retaining a U.S. agent. However, we would like to take this opportunity to provide FDA with additional economic information with regard to the costs associated with the overall registration process.

As previously noted, BC's foreign affiliate facilities designated BC as the U.S. agent in charge and assigned a BC individual with registration responsibility. Thus, BASF AG foreign facilities relied on a U.S. business affiliate (BC) for all actions required to comply with the IFR and no direct costs were incurred by the foreign facility for the hiring and retaining of a U.S. agent. However, the cost to BC as the agent in charge with designated registration responsibility was substantial. BC has estimated the first year cost to complete the registration process for foreign affiliate facilities to be $1800.00 per facility (see attachment). This figure is approximately 20% higher than FDA's estimated first year cost of $1500.00 per facility and does not include costs associated with on-going management of change to insure updated information is provided to FDA within the 60-day window allowed.

Although we acknowledge that the cost of the actual electronic registration process is minimal, BC believes FDA underestimated the time needed for the analysis of such a complex rule and it's implications for large multi-facility corporations. For example, 120 hours alone were needed to analyze the rule including time spent attending conference and seminars, meeting with internal personnel and outside trade associations, and drafting and submitting comments to the proposal. Half of this time was estimated to be costs associated with the registration of foreign facilities. Numerous hours were needed to identify the facilities required to register and disseminate information to them, to develop systems to ensure timely updates, and to draft and finalize agreements delegating the registration responsibility to an employee of the U.S. agent in charge.

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In addition, we also believe that FDA underestimated the hourly wage associated with the registration process for many foreign facilities. As noted above, BC's acts as the U.S. agent and assume registration responsibility for foreign affiliate facilities. Under these circumstances the hourly wage rate is similar to the hourly rates used for the computation of costs for domestic facilities. Given the importance of the rule and implications of non-compliance, BC utilized three employees working as a team for the registration process. One employee was an attorney and two were managerial level. Given the make-up of the team, BC used an average of $100.00 per hour as opposed to FDA's average rate of $82.00.

Given BC's analyses of the cost associated with acting a the U.S. agent and assuming registration responsibilities we believe the cost to foreign facilities of hiring and retaining a U.S. agent would even be higher than those estimated above. Domestic facilities assuming these responsibilities for their foreign affiliate facilities have the advantage of being familiar with the general U.S. regulatory schemes and compliance activities. Thus, we believe that less time would be needed by the domestic firm to complete the analyses of the rule and put a compliance plan in place.

Further cost estimates are provided in the attachment. You will note that the attachment includes cost associated with the registration process for both domestic and foreign affiliate facilities. BC estimates that first year cost for domestic registrations was $1300.00 per facility. This figure is significantly higher than FDA's estimated figure of $106.00 per facility. BC believes the reason for the huge discrepancy is similar to that expressed for foreign affiliate facilities and that FDA greatly underestimated the time needed by large, multi-facility corporations to ensure compliance with the registration requirements.

Finally, we note that in addition to the costs incurred registering our foreign affiliate and domestic facilities, BC also incurred costs as a result of our stewardship efforts with third party suppliers. Although BC did not assume responsibility for the registration of these facilities, expenses were incurred educating these facilities about the requirements and assisting them with the registration process. BC is not providing data related to this process. However, BC is not aware that FDA considered these expenses when calculating registration cost for foreign or domestic facilities.

In conclusion, BC acknowledges that the information provided in these comments is broader than that specifically requested by FDA in the notice of the reopening of the comments period for the interim final rule "Registration of Food Facilities under the Public

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Health Security and Bioterrorism Preparedness and Response Act of 2002." However, we believe that FDA estimates of the overall cost associated with the registration process were low and appreciate the opportunity to provide FDA with additional information in support of our belief. We respectfully request that FDA consider these comment when improving its economic analysis and issuing a final rule.

Sincerely,

Claudia Skarbek Elias

Claudia Skarbek Elias
Regulatory Manager

Attachment

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BC's Computation of Cost for the Registration Process for Foreign Affiliate and Domestic Facilities

	Foreign Affiliate	Domestic
Number of facilities	13	10
Time on the analysis of the rule (including time spent on attending teleconferences, seminars, etc., meeting with trade associations and commenting on proposal)	60 hours	60 hours
Time spent on determining implications for business (including identifying those facilities required to register and development of systems designed to ensure timely updates)	65 hours	45 hours
Time spent on disseminating information to affected facilities (including the drafting and signing of agreements for foreign facilities)	96 hours	18 hours
Time spent on actual registration process (including completing forms and submitting electronically)	13 hours	10 hours
TOTAL HOURS SPENT	234 hours	133 hours
Hourly Wage (average of attorney and managerial wages)	$100.00	$100.00
First Year Cost Per Facility	$1,800.00	$1,330.00

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